UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 09/311,689 | 05/13/99 | MAU | A 05/1R2 |

HM22/0212

STEVEN J. CALLISTEIN
PIONEER HI-BRED INTERNATIONAL INC
7100 NW 62ND AVE
PO BOX 1000
JOHNSTON IA 50131-1000

| EXAMINER | |
|---|---|
| KERR,K | |
| ART UNIT | PAPER NUMBER |
| 1652 | 11 |

DATE MAILED: 02/12/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

| Office Action Summary | Application No. 09/311,689 | Applicant(s) Rao et al. |
|---|---|---|
| | Examiner Kathleen Kerr | Group Art Unit 1652 |

X Responsive to communication(s) filed on *1/16/01* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

X Claim(s) *1-25, 28-47, 49, 50, and 52-95* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

X Claims *1-25, 28-47, 49, 50, and 52-95* are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

*--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---*

## DETAILED ACTION

### *Application Status*

1. A preliminary amendment (Paper No. 10) was filed on January 16, 2001, which deleted Claims 26-27, 48, and 51 added new claims 52-95. Claims 1-25, 28-47, 49-50, and 52-95 are pending in the instant application.

The instant Office action is a supplemental restriction requirement in view of Applicants' amendments and Applicants' Exhibit A which identified the similarities among the numerous sequences claimed. Said supplemental requirement is at the discretion of the Examiner (see MPEP 802 and 37 CFR 1.142) and is deemed appropriate and necessary in view of the amended subject matter of the instant claims.

### *Restriction*

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8 and 52-53, drawn to seeds comprising chymotrypsin inhibitor-2 (CI-2) polypeptides and food or feed compositions thereof, classified in class 800, subclass 295.

II. Claims 9 and 54-55, drawn to CI-2 polypeptides having particular molar amino acid concentrations, classified in class 530, subclass 300.

III. Claims 10-32, 56-58, and 61-86, drawn to CI-2 polypeptides related to SEQ ID NOs: 2, 4, 6, 8, 10, 12, 1, 16, 18, or 20, classified in class 530, subclass 300.

IV. Claims 33-43 (33a), drawn to nucleic acids encoding CI-2 polypeptides as described in Claim 1, classified in class 536, subclass 23.1.

V. Claims 33-43 (33b, d, f-i), drawn to nucleic acids encoding CI-2 polypeptides as described by SEQ ID NOs: 2, 6, 8, 10, 12, 14, 16, 18, or 20, classified in class 536, subclass 23.1.

VI. Claims 33-43 (33c), drawn to nucleic acids which can be amplified by SEQ ID NOs: 21 and 22, classified in class 536, subclass 23.1.

VII. Claims 33-43 (33e), drawn to nucleic acids encoding CI-2 polypeptides with particular amino acid content classified in class 536, subclass 23.1.

VIII. Claims 44-45, drawn to methods for increasing the essential amino acid content in a plant relating to the polypeptide of Claim 10, classified in class 800, subclass 278.

IX. Claim 46, drawn to methods of increasing expression levels of a polypeptide in a transgenic plant cell, classified in class 800, subclass 278.

X. Claims 47 and 49, drawn to methods of increasing the nutritional value of a feed or food source, classified in class 800, subclass 295.

XI. Claim 50, drawn to methods of increasing the nutritional value of a CI-2 polypeptide to enhance its nutritional value, classified in class 530, subclass 300.

XII. Claims 59-60, drawn to CI-2 polypeptides having particular lysine concentrations, classified in class 530, subclass 300.

XIII. Claims 87-92, drawn to CI-2 polypeptides derivatives having a certain number of modifications, classified in class 530, subclass 300.

XIV. Claims 93-95, drawn to method for increasing the essential amino acid content in a plant [polypeptide] (apparent typographical error), classified in class 800, subclass 278.

3. The inventions are distinct, each from the other, because of the following reasons. First the Examiner will identify closely related groups (SuperGroups) and their differences, then the Examiner will distinguish between SuperGroups.

- SuperGroup A: Group I - seed claims
- SuperGroup B: Groups II, III, XII, and XIII - polypeptide claims
- SuperGroup C: Groups IV, V, VI, and VII - nucleic acid claims
- SuperGroup D: Groups VIII, IX, X, XI, and XIV - various method claims

SuperGroup A is a single Group drawn to seed claims and needs no further distinction.

Members of SuperGroup B are all polypeptide Groups, all classified together by the U.S. Classification system; this broad classification is for any polypeptide between 3 and 100 amino acids in length. The Examiner notes that the scope of these Groups may overlap; however, the

scope of these Groups are not the same. Furthermore, each set of polypeptides is distinct from every other set of polypeptides due to their distinct structural features, namely their amino acid sequences required. For example, while SEQ ID NO:2 may contain the appropriate amino acid composition within the limitations of Claim 9, the sequence of such amino acids are not a limitation. Thus every Group in SuperGroup B is distinct, each from the other, based on structural distinctness. Moreover, examining any two of these two Groups together presents an **enormous** search burden on the Examiner. These Groups, each independently, present a **large** search burden on the Examiner due to the numerous SEQ ID NOs, various amino acid composition criteria, or various homologies to known sequences. However, within the Groups appear, on their face, to not be distinct, and thus are grouped together since restriction is not allowed in the absence of distinction or independence. Thus, each member of SuperGroup B is distinct, each from the other.

Members of SuperGroup C are all nucleic acid Groups, all classified together by the U.S. Classification system; this broad classification is for any nucleic acid fragment. The Examiner notes that the scope of these Groups may overlap; however, the scope of these Groups is not the same. Furthermore, they are just as distinct as the polypeptides as noted above for the same reasons. Thus, each member of SuperGroup C are distinct, each from the other.

Members of SuperGroup D are all methods relating to CI-2 polypeptides. Clearly, Groups X and XI are distinct as evidenced by their distinct U.S. classifications; however, Groups VIII, IX, and XIV are all similarly grouped. Clearly methods of increasing expression levels (Group

IX) are distinct from methods of increasing the essential amino acid content in a plant (Groups VIII and XIV) by virtue of their distinct method steps using different reagents to produce different products. Moreover, Groups VIII and XIV are distinct by virtue of their use of distinct reagents, namely the distinct polypeptides in the methods. Thus, each member of SuperGroup D is distinct, each from the other.

SuperGroup A is distinct from each member of SuperGroups B and C although these SuperGroups are related by virtue of Group I containing CI-2 polypeptide inhibitors, SuperGroup B containing different CI-2 polypeptide inhibitors, and SuperGroup C containing nucleic acids encoding different CI-2 polypeptide inhibitors. The polypeptides found in the seeds are distinct from the polypeptides of SuperGroup B, thus no combination/subcombination relationship exists. Furthermore, these SuperGroups are distinct as evidenced by their distinct class/subclass classification. Thus, SuperGroup A is patentably distinct from every member of SuperGroups B and C.

SuperGroup A is distinct from the methods of Groups VIII, IX, XI, and XIV (SuperGroup D without Group X) although these SuperGroups are related by virtue of Group I containing CI-2 polypeptide inhibitors. The methods of Groups VIII, IX, XI, and XIV do not use the seeds of SuperGroup A as reagents nor do they produce the seeds of SuperGroup A. Thus, SuperGroup A is patentably distinct from Groups VIII, IX, XI, and XIV.

SuperGroup A is related to Group X as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using

the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the seeds can be used in other processes such as in the production of transgenic plants. Thus, SuperGroup A is patentably distinct from Group X. Note possible rejoinder below.

Members of SuperGroup B and SuperGroup C are unrelated when describing different polypeptides. However, some members of SuperGroup B and SuperGroup C are related by virtue of the fact that the polypeptides are encoded by the polynucleotides. The DNA molecule has utility for the recombinant production of the polypeptide in a host cell. Although the DNA and the polypeptide are related, they are distinct inventions because the polypeptide product can be made by other and materially distinct processes, such as chemical synthesis. Furthermore, DNA can be used for processes other than the production of polypeptide, such as nucleic acid hybridization assays. Therefore, all members of SuperGroups D and C are patentably distinct, each from the other.

Members of SuperGroups B and C are unrelated to the methods of SuperGroup D because the products of SuperGroups B and C are not used in the methods of SuperGroups D - not specifically as reagents of products since the polypeptides used in the methods do not directly related to particular polypeptide or nucleic acid claims. Thus, every member of SuperGroups B and C are patentably distinct from every member of SuperGroup D, each from the other.

***Notice of Possible Rejoinder***

4. The Examiner notes that if Claim 1 is found directed to an allowable product, then Claim 47, which is directed to the process of using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also MPEP 821.04, *In re Ochiai,* and *In re Brouwer*). Since process Claim 47 would be rejoined and fully examined for patentability under 37 CFR 1.104, applicants are instructed to amend said claim as deemed necessary according to rejections made against the elected claims.

***Election***

5. Applicants are advised that the reply to this requirement MUST include an election of the invention (Group, not SuperGroup) to be examined, even though the requirement be traversed (37 CFR 1.143).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

*Conclusion*

6. Applicants must respond to the instant supplemental restriction requirement by electing a Group (not a SuperGroup) to be examined to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Kathleen M. Kerr whose telephone number is (703) 305-1229. The Examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone number for this Group is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

KMK

February 7, 2001